NDC Reservation

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Overview

- Who should Reserve
- When to Reserve
- Benefits
- How to reserve an NDC (National Drug Code) in CDER Direct

Who Should Reserve?

- Preparation for a product launch – Pre-printing labels
- CMOs responsible for the PLD's drug listing
- Reservations should be used if the company is uncertain of marketing status, unsure of the product's final approved formulation, and the final physical characteristics (color, shape, imprint etc.)

When to Reserve

- If the NDC appears on the label:
- Prior to final labeling approval and printing
- The reservation is not required prior to the actual listing submission
- Do not reserve an NDC if you do not intend to start the commercial distribution within 2 years.

Benefits

- Preparation for a product launch
- Once accepted, the proposed NDC is reserve for 2 years
- Prevention of duplicate and formatting issues before drug listing
- CMOs can reserve and NDC using a PLD’s labeler code

Tips Regarding Reservation

- The labeler code included in the reservation SPL, should be a labeler code that is electronically assigned by and submitted to FDA.

- Required data elements for NDC Reservation:

  – Labeler Name, Labeler DUNS, NDC Product Code, Non Proprietary Name, Dosage Form, Marketing Status, Reserved Until Date, and 1 Active Ingredient.

Tips Regarding Reservation

- NDCs under the same labeler code can be reserved on the same NDC Reservation SPL
- Once accepted, the proposed NDC is reserved
- NDC is reserved at the product level:
  - Labeler Code and Product Code
  - No packaging information needed
- No additional data is “required” for NDC Reservation

Tips -Continued

- Marketing Status for all reserved NDC is “New” or “Reserved”
- To convert an NDC Reservation SPL to a Listing SPL, the Marketing Status must be switched from “Reserved” to “Active”
- A Reserved NDC that is no longer needed can be canceled
- To cancel an NDC Reservation, change the Marketing Status from “Reserved” to “Cancel

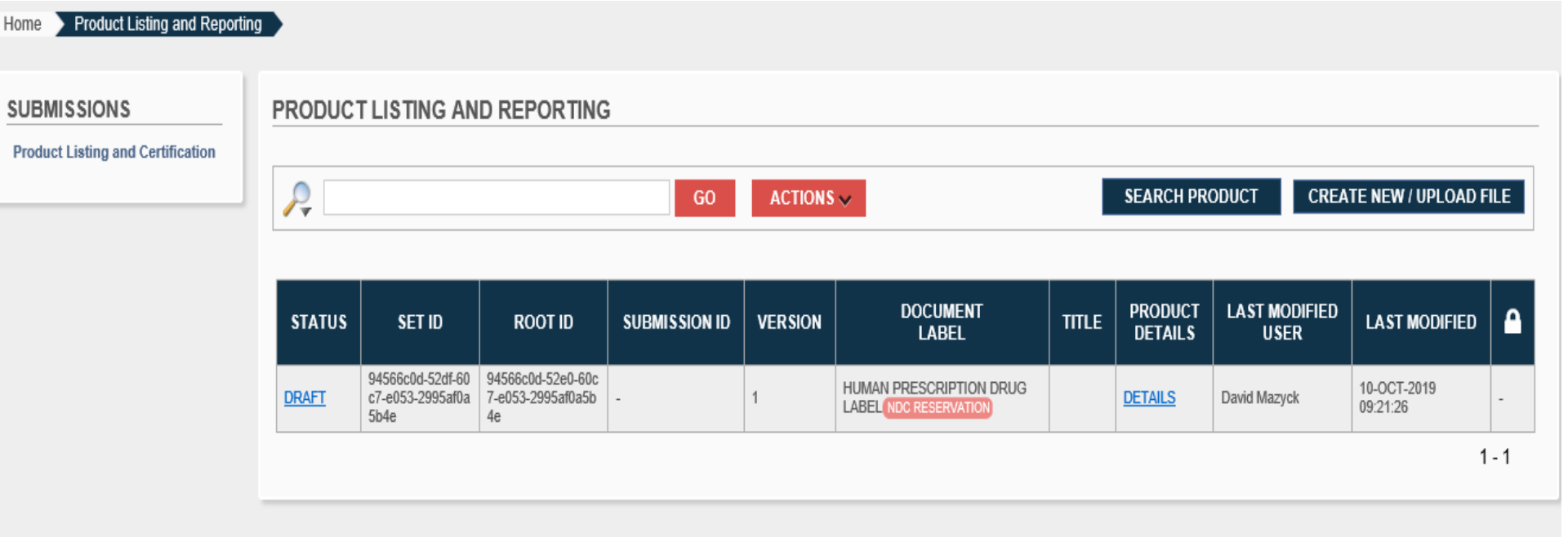
Tips -Continued

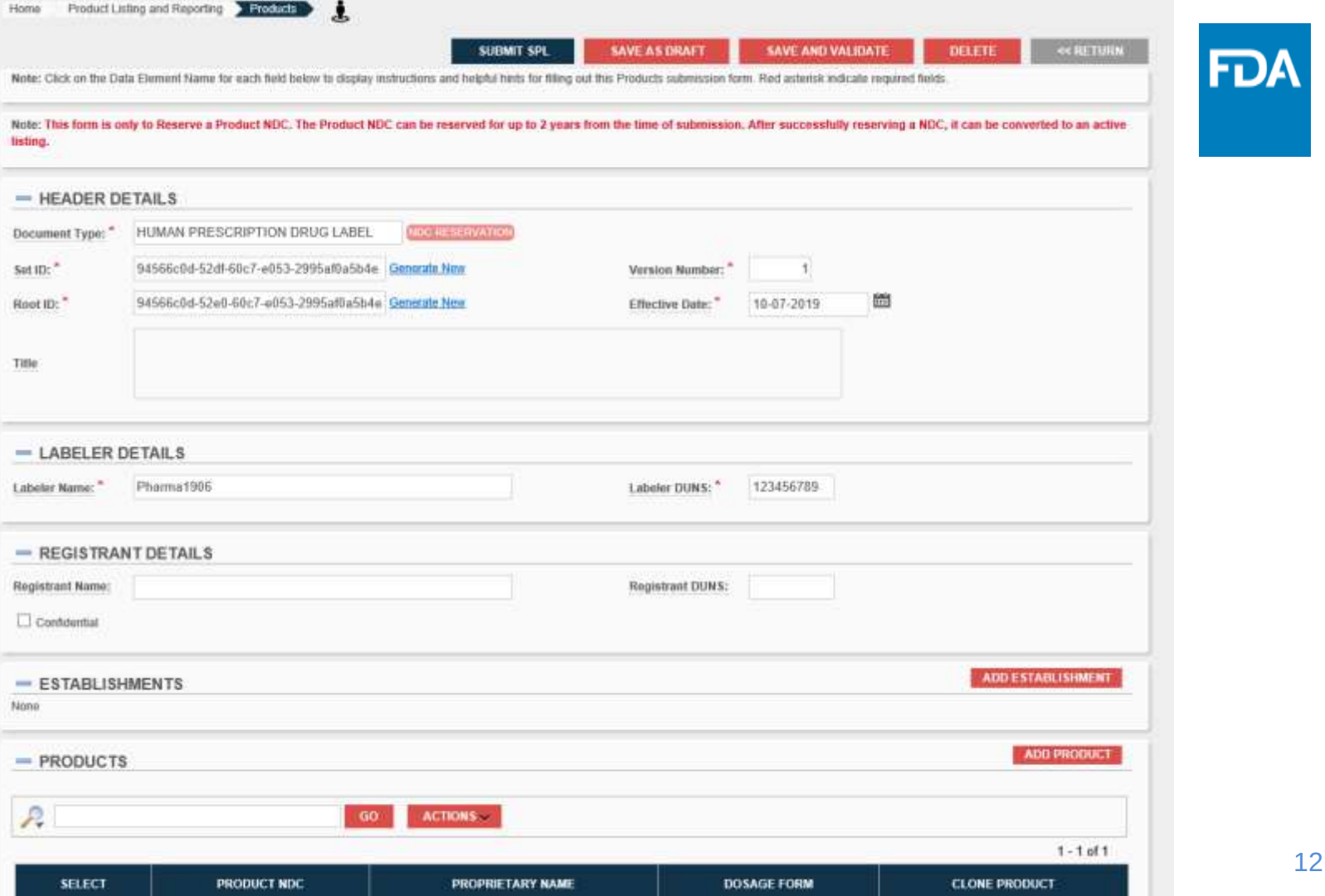
- Cancelling an NDC Reservation is effective on day of submission
- A reserved NDC, will not be available for reservation or listing of other products.
- An NDC Reservation cannot be submitted for an NDC which has already used.
- A previously reserved NDC becomes available once its reservation is canceled

Key Facts

- NDC Reservation is not drug listing
- Limited data elements required
- Data will not be published until properly listed
- Effective date is the Submission date
- Reserved until date can be up to 2 years after the Effective Date

NDC Reservation




Home
Product Listing and Reporting
Products
SUBMIT SPL
SAVE AS DRAFT
SAVE AND VALIDATE
DELETE
<< RETURN
Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Products submission form. Red asterisk indicate required fields.
Note: This form is only to Reserve a Product NDC. The Product NDC can be reserved for up to 2 years from the time of submission. After successfully reserving a NDC, it can be converted to an active listing.
HEADER DETAILS
Document Type: * HUMAN PRESCRIPTION DRUG LABEL
NDC RESERVATION
Set ID: * 94566c0d-52df-60c7-e053-2995af0a5b4e Generate New
Version Number: * 1
Root ID: * 94566c0d-52e0-60c7-e053-2995af0a5b4e Generate New
Effective Date: * 10-07-2019
Title
LABELER DETAILS
Labeler Name: * Pharma1906
Labeler DUNS: * 123456789
REGISTRANT DETAILS
Registrant Name:
Registrant DUNS:
Confidential
ESTABLISHMENTS
ADD ESTABLISHMENT
None
PRODUCTS
ADD PRODUCT
GO
ACTIONS
1 - 1 of 1
SELECT
PRODUCT NDC
PROPRIETARY NAME
DOSAGE FORM
CLONE PRODUCT

PRODUCT DATA ELEMENTS

NDC Product Code: * 54321-000

Proprietary Name: Drug 1

Suffix:

Non Proprietary Name: * Drug 1

DEA Schedule: -Select DEA Schedule-

Dosage Form: * CAPSULE

Route of Administration:

AURICULAR (OTIC)
BUCCAL
CONJUNCTIVAL
CUTANEOUS
DENTAL
ELECTRO-OSMOSIS

Source NDC:

MARKETING DETAILS

Marketing Status: * RESERVE

Reserved Until Date: * 10-04-2021

Marketing Category: OTC monograph final

Application Number/
Regulatory Citation:

INGREDIENTS

ADD INGREDIENT

Note: * At least one active ingredient is required

NDC Reservation

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

INGREDIENT DETAILS

Denominator Strength: *

Unit of Measure: * -- Select One --

Type: * -- Select One --

Ingredient UNII - Name: *

Strength: *

Unit Of Measure: * -- Select One --

Active Moiety: *

ADD ACTIVE MOIETY

Reference Ingredient: *

Challenge Questions

- NDC reservation is required to facilitate the listing submission. T/ F
- The reservation date may be up to 2 years after the effective date. T/F
- Reservation data is published on the NDC directory. T/f

Contact Us:

eDRLS@fda.hhs.gov

CDER Direct Product Listing

Troy Cu
Technical Information Specialist
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Overview

- Who must list
- When
- Listing submission and common errors
- Updating listing and Delisting
- Summary
- Helpful resources

“Who”

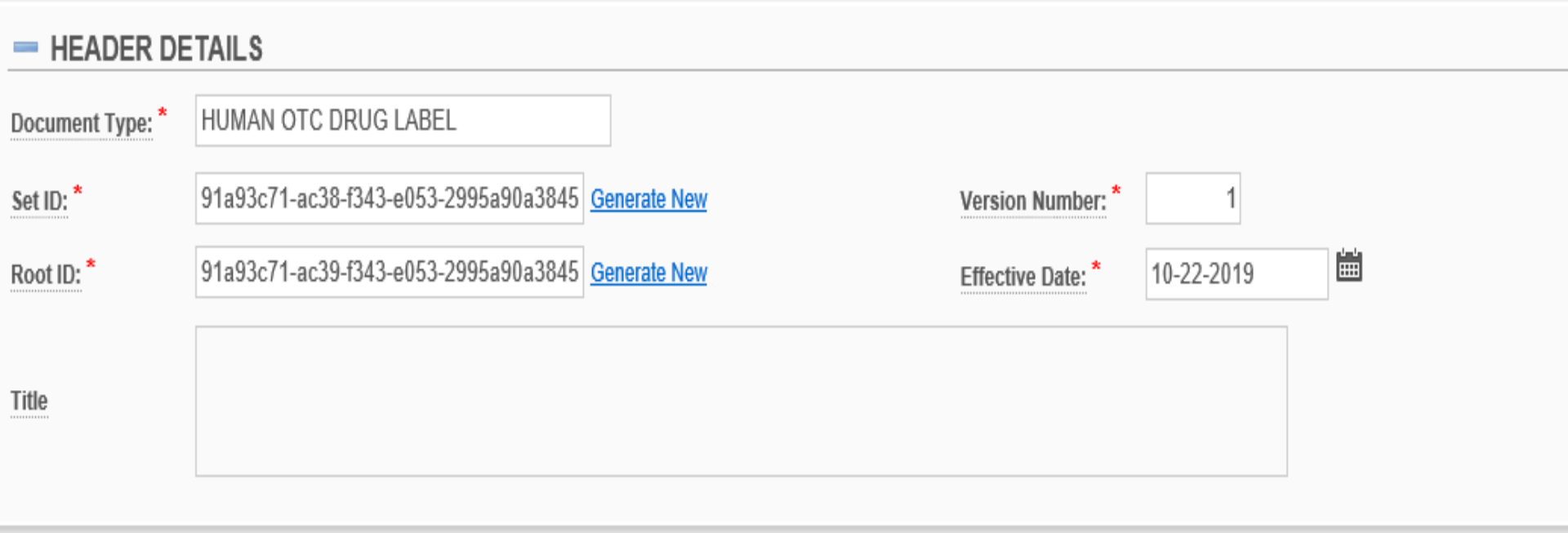
- Unless exempt, ALL registrants must list all drugs manufactured for commercial distribution
- Contract manufactures (CMO) must list under their own labeler code

“When”

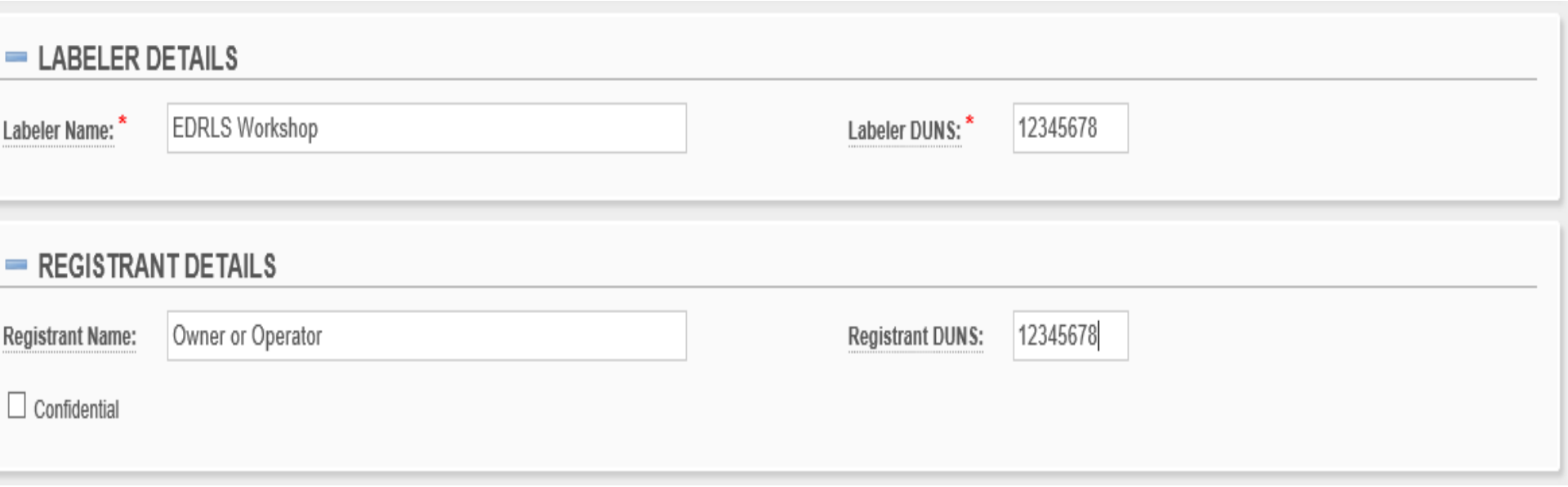
- Initial- Listing information must be submitted within 3 days of the initial registration
- Updates- You can update any changes to the listing every June and December, preferably ASAP.
- Annual listing certification- Accepted updates to the listing certifies your listing for the calendar year and the next calendar year

Listing Submission and common errors

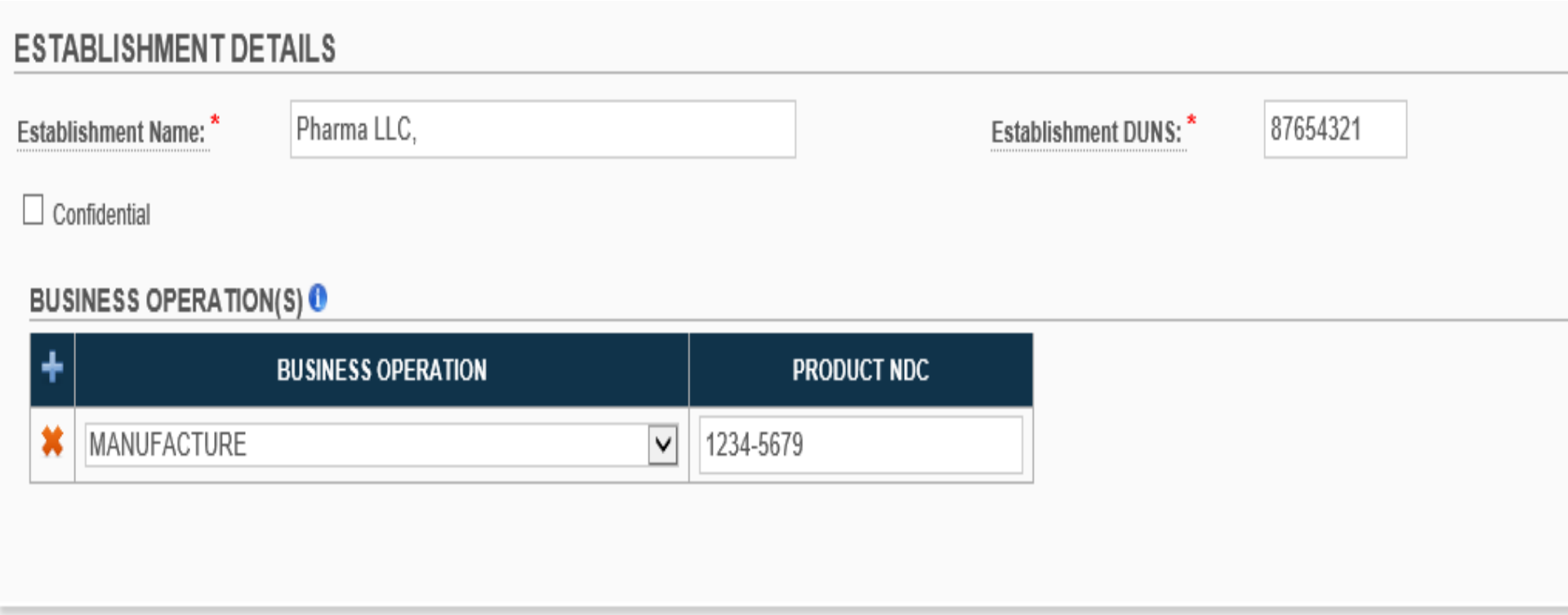
Header details



Labeler and Registrant details



Establishment details

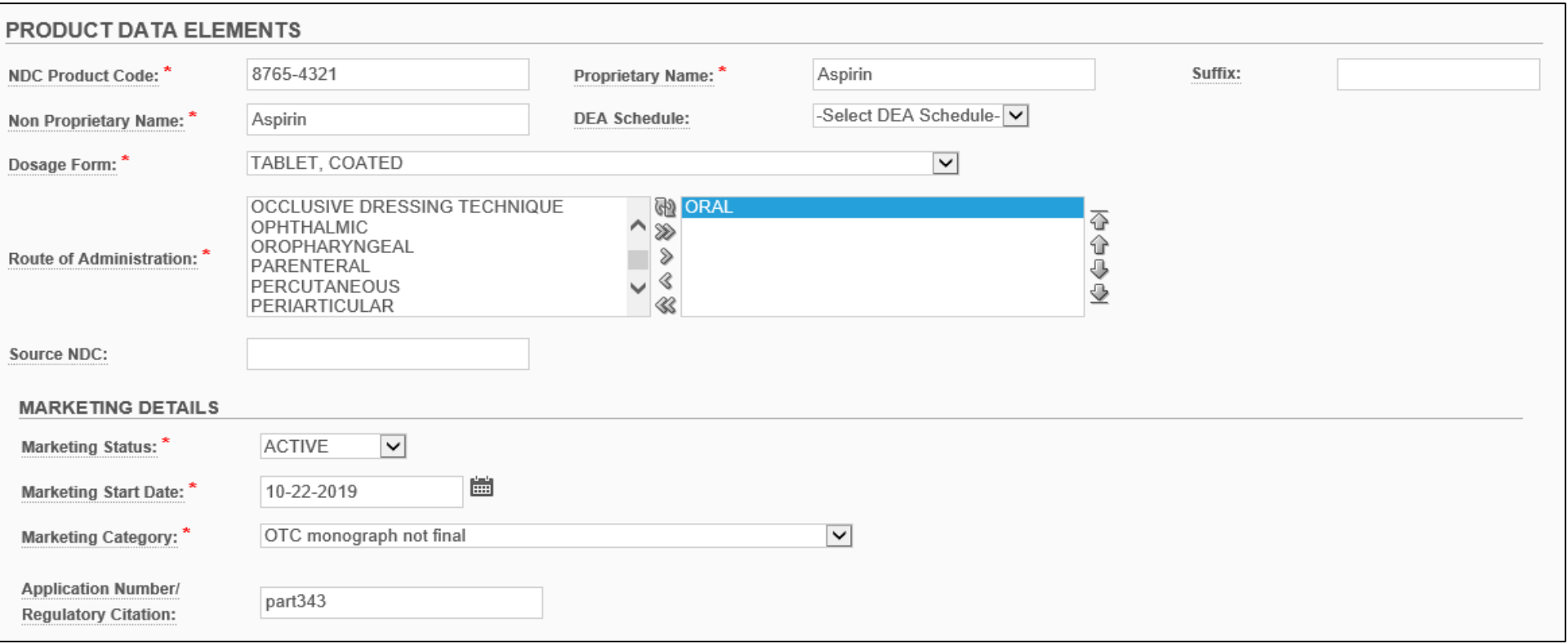


Establishment common errors

- If CDER regulated: A listed establishment operation must be linked to a product, except for Human Compounded Drug Label (75031-5)

- The ***establishment ID*** must match the ID of an "establishment registration" in the same or previous calendar year

Product details



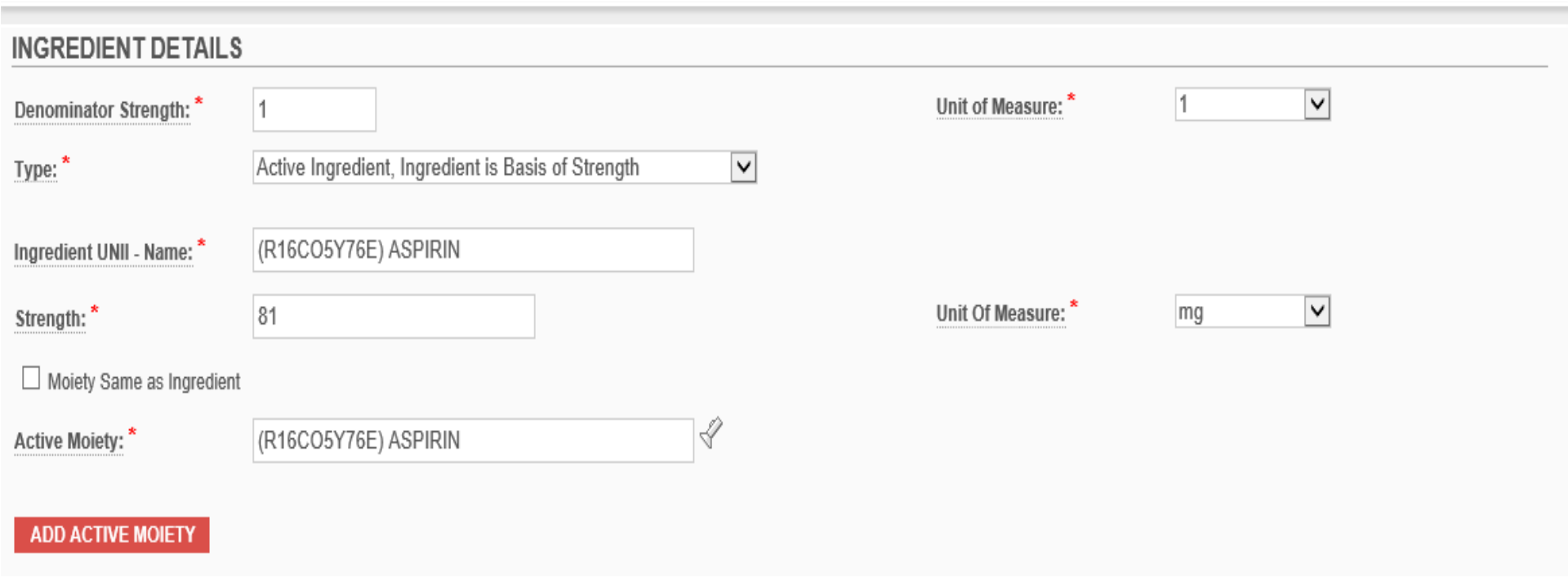
Product details common errors

- First segment (NDC/NHRIC labeler code) must match a labeler code associated with the Labeler id (labelers DUNS Number) in a previously submitted NDC/NHRIC Labeler Code or NDC Labeler Code - Animal Drug SPL document, except for parts
- The set id must not be associated with any top level product with a different NDC Labeler Prefix

Product details common errors

- If the NDC product/item code was previously submitted, then the product dosage form is same as in the most recent submission for this NDC product/item code
- If the NDC product/item code was previously submitted, then the product name is same as in the most recent submission for this NDC product/item code

Product Ingredient Details



Product characteristics details

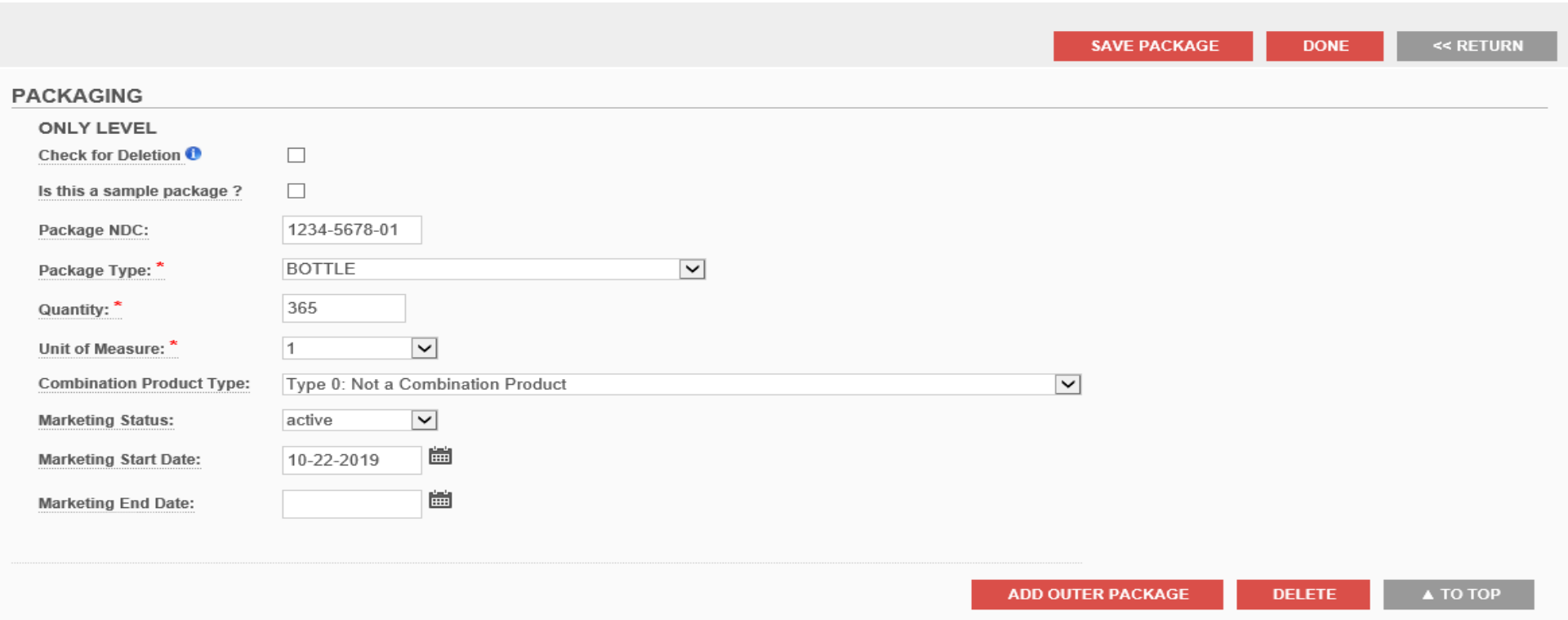
CHARACTERISTICS

ADD CHARACTERISTIC

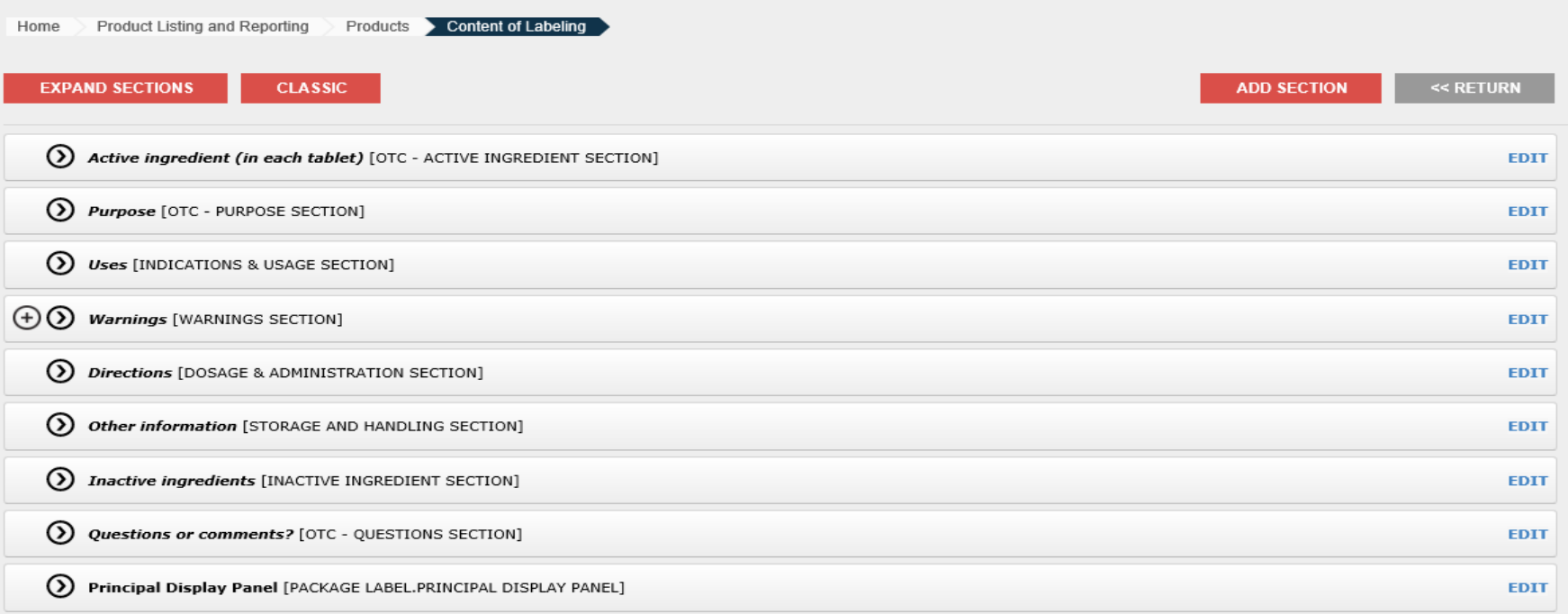
row(s) 1 - 5 of 5

	CHARACTERISTIC	VALUE	ADDITIONAL DESCRIPTION
	SPLCOLOR	PINK	-
	SPLIMPRINT	L	-
	SPLSCORE	1	-
	SPLSHAPE	ROUND	-
	SPLSIZE	6 mm	-

Product packaging details

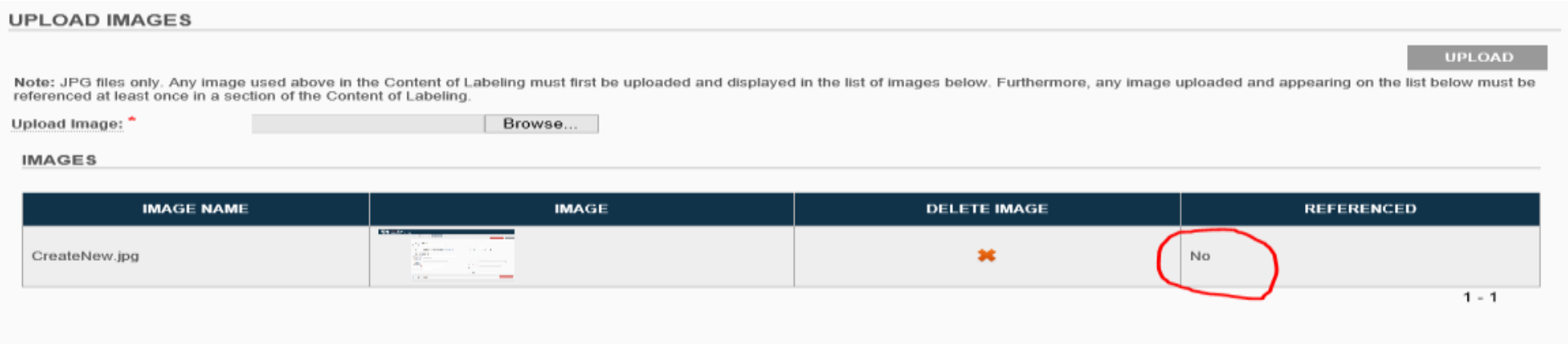


Product content of labeling



Product details common errors

- All image files associated with the SPL document are actually referenced from that SPL document.



Product details common errors

- If the NDC product/item code was previously submitted, then the product characteristic of flavor is the same as in the most recent submission for this NDC product/item code

- If the package item code has been previously submitted, then the package form code and quantity value and unit must be the same as in the most recent submission for this item code

Product details common errors

- The strength numerator must be based on mass (e.g., mg or g) and not volume (e.g. mL or L), except for ingredients such as water, alcohol, and gases

- Unit of the numerator (for package amount) of the initial package must be the same as the units for the denominators of all the ingredient quantities (strengths)

Updating a Previous listing

- Create a new version of the most recent accepted submission
- Do not change the Set ID!
- A new Root ID and version number will generate automatically
- Modify all listing data elements and labeling information as appropriate
- Submit

Delisting a product

- Create a new version of the most recent accepted submission
- Change the marketing status from “Active” to Complete
- Enter the end marketing date for the product (e.g., Expiration date of last lot in distribution)
- Submit

Summary

- Listing allows FDA to maintain an inventory of all drugs commercially distributed in the U.S and their representative labeling
- Listing data is also used by the public and other organizations in academia and industry
- Remember to delist when no longer in commercial distribution
- Have a standard operation procedure or system in place to verify the accuracy of listing at least twice a year

In a Nutshell

WE ALL NEED THIS INFORMATION TO BE

ACCURATE, COMPLETE AND UP TO DATE!

Helpful resources

- Electronic Drug Registration and Listing instructions
- Strength Conversion in Drug Listing
- National Drug Code Directory
- Electronic Code of Federal Regulations
- edrls@fda.hhs.gov

Challenge Questions

- Are you required to provide establishment information in product listing- T/F
- Product listing can be listed without labeler code- T/F
- Content of labeling is not required for product listing- T/F

CDER Direct
503B Product Reporting

LCDR Soo Jin Park, PharmD., MS

Office: CDER/OC/OPRO/DRLS

Agenda

- Regulation
  - 503B Registration
  - 503B Product Reporting
- Common Errors
- Summary
- Related Resources

Regulations

- **The Drug Quality and Security Act**
  - Created a new section 503B in the FDCA
  - A compounder can become an “outsourcing facility”
- **Outsourcing Facility is…**

Regulations

- **Outsourcing Facilities are:**
  - Exempted from FDA approval requirements
  - Exempted from certain labeling requirements
  - NOT exempted from cGMP Requirements

Regulations

- **Upon Registration, an outsourcer must:**
  - Submit an initial product reporting of all compounded products
  - Must submit in June and December of each year

What to include in PR

- Active ingredient and strength of active ingredient per unit
- Source of the active ingredient and NDC of the source drug or bulk active ingredient, if available
- Dosage form and route of administration
- Package description
- Number of individual units produced
- NDC number of the final product, if assigned

Product Reporting Submission and Common Errors

PR Common Errors

- Ingredient source product item code (source NDC) must have been previously submitted
  - Must be a known listed product
  - Verify listing status of source NDC (IMPORTANT!)

PR Common Errors

- The source of the active ingredient identified by the item code (source NDC product code) must have that same active ingredient as the compounded drug product

  - Bulk or finished drugs

PR Common Errors

- If the active ingredient is in the active-ingredient-active-moiety-validation-list

  - Active moiety and basis of strength must be the corresponding active moiety and basis of strength respectively in this list

PR Common Errors

- If the NDC product/item code was previously submitted, then following must remain the same as in the most recent submission for this NDC product/item code:

- Product Name

- Active ingredient UNIIs and active ingredient strengths

- Generic Name

Summary

- Required to submit product reporting in June and December
- Source NDC is REQUIRED for all source drug ingredients
- Data Files for Unfinished Drugs are available on FDA's National Drug Code (NDC) Directory: https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm
- Prepare ahead of time to get ingredient NDCs and verify listing status

Helpful Resources

- **The Drug Quality and Security Act: Human Drug Compounding Outsourcing Facility:** http://wcms.fda.gov/FDAgov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm

- **Guidance for Industry: Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Final Guidance):** http://wcms.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM424303.pdf

Helpful Resources

- **Electronic Drug Registration and Listing Instructions:** https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions

- **Human Drug Compounding Website:** https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

- **503B Compounding Dashboard:** http://wcms.fda.gov/FDAgov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm

Helpful Resources

- **Publication of Product Reporting:** https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm393571.htm

- **National Drug Code Directory:** https://www.fda.gov/drugs/informationondrugs/ucm142438.htm

Contact Us!

- **eDRLS Helpdesk:** edrls@fda.hhs.gov
- **CDER Direct Helpdesk:** CDERdirect@fda.hhs.gov
- **Compounding Helpdesk:** Compounding@fda.hhs.gov


THANK
YOU